



Contraceptive Coverage Requirements Under Section 2713 of the Public Health Service Act



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Disclaimer

The information provided in this presentation is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This presentation summarizes current policy as of the date it was presented. We encourage readers to refer to the applicable statutes, regulations, and appropriate interpretive materials for complete and current information.

Coverage of Preventive Services

Section 2713 of the Public Health Service Act (PHS Act) and its implementing regulations require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover without cost sharing:

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be “in effect” after it has been adopted by the Director of the CDC. A recommendation is considered to be for “routine use” if it appears on the Immunization Schedules of the CDC.

Coverage of Preventive Services

(continued)

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- **With respect to women, such additional preventive care and screenings not included in the recommendations of the USPSTF described above as provided for in comprehensive guidelines supported by HRSA.**

In addition, under section 3203 of the Coronavirus Aid, Relief and Economic Security (CARES) Act and its implementing regulations, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover, without cost sharing requirements,

- Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19), and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use).

HRSA Guidelines

- HRSA is responsible for developing comprehensive guidelines for preventive care and screenings with respect to women.
- The 2019¹ HRSA-supported Women’s Preventive Services Guidelines state:
 - Adolescent and adult women should have access to the full range of female-controlled FDA-approved, cleared or granted contraceptive methods²; effective family planning practices, and sterilization procedures to prevent unintended pregnancy and improve birth outcomes; and
 - Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management and evaluation as well as changes to, and removal or discontinuation of, the contraceptive method), and that instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

¹ <https://www.hrsa.gov/womens-guidelines-2019>

² The Departments note that the FDA approves, clears, and grants contraceptive products and not methods.

HRSA Guidelines

- On December 30, 2021, HRSA accepted updates to the existing guidelines, which are effective for plan and policy years beginning on or after December 30, 2022.
- With respect to contraception, the 2021³ HRSA-supported Women's Preventive Services Guidelines recommend:
 - Adolescent and adult women have access to the full range of FDA-approved, granted, or cleared contraceptives, effective family planning practices, and sterilization procedures as part of contraceptive care;
 - Contraceptive care includes screening, education, counseling, provision of contraceptives (including in the immediate postpartum period), follow-up care (e.g., management, evaluation, and changes, including the removal, continuation, and discontinuation of contraceptives); and
 - Instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

³ <https://www.hrsa.gov/womens-guidelines>

Contraceptive Categories

- Non-grandfathered plans and issuers must cover, without cost sharing, at least one form of contraception in each of the categories of contraceptives described in the HRSA-Supported Guidelines.
- Any FDA-approved, cleared, or granted contraceptive products that are determined by an individual's attending provider to be medically appropriate for such individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported Guidelines, must be covered without cost sharing.
- This coverage must also include items and services that are integral to the furnishing of a recommended preventive service, including coverage for anesthesia for a tubal ligation procedure or pregnancy tests needed before provision of certain forms of contraceptives, such as an intrauterine device (also known as an IUD), regardless of whether the items and services are billed separately.

Contraceptive Categories (continued)

The contraceptive categories identified by the 2019 Guidelines include:

- (1) sterilization surgery for women
 - (2) surgical sterilization via implant for women
 - (3) implantable rods
 - (4) copper intrauterine devices
 - (5) intrauterine devices with progestin (all duration and doses)
 - (6) the shot or injection
 - (7) oral contraceptives (combined pill)
 - (8) oral contraceptives (progestin only)
 - (9) oral contraceptives (extended or continuous use)
 - (10) the contraceptive patch
 - (11) vaginal contraceptive rings
 - (12) diaphragms
 - (13) contraceptive sponges
 - (14) cervical caps
 - (15) female condoms
 - (16) spermicides
 - (17) emergency contraception (levonorgestrel)*
 - (18) emergency contraception (ulipristal acetate)*
- And any additional contraceptives approved, cleared, or granted by the FDA.

*Note: emergency contraception (including OTC products) must be covered without cost sharing if prescribed; including when prescribed for advanced provision

Contraceptive Categories (continued)

The contraceptive categories identified by the 2021 Guidelines include:

- (1) sterilization surgery for women
 - (2) implantable rods
 - (3) copper intrauterine devices
 - (4) intrauterine devices with progestin (all duration and doses)
 - (5) injectable contraceptives
 - (6) oral contraceptives (combined pill)
 - (7) oral contraceptives (progestin only)
 - (8) oral contraceptives (extended or continuous use)
 - (9) the contraceptive patch
 - (10) vaginal contraceptive rings
 - (11) diaphragms
 - (12) contraceptive sponges
 - (13) cervical caps
 - (14) condoms
 - (15) spermicides
 - (16) emergency contraception (levonorgestrel)*
 - (17) emergency contraception (ulipristal acetate)*
- And any additional contraceptives approved, granted or cleared by the FDA

*Note: emergency contraception (including OTC products) must be covered without cost sharing if prescribed; including when prescribed for advanced provision



Reasonable Medical Management

- Plans and issuers may utilize reasonable medical management techniques only within a specified category of contraception and only to the extent the HRSA-Supported Guidelines do not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service that is a contraceptive service or FDA- approved, cleared, or granted product.
- Plans and issuers must cover, without cost sharing, at least one form of contraception in each category that is described in the HRSA-Supported Guidelines (or, with respect to contraceptive categories not described in the HRSA-Supported Guidelines, at least one form of contraception in a group of substantially similar services or products that are available and medically appropriate for the individual).
- Medical management will not be considered reasonable unless:
 - there is an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome, and
 - The plan or issuer covers a service or FDA-approved, cleared, or granted product determined to be medically necessary with respect to an individual, as determined by the individual’s attending provider.

Examples of Unreasonable Medical Management

Examples of unreasonable medical management techniques (which are the subject of a number of complaints regarding plans and issuers, as well as their pharmacy benefits managers or other service providers) may include situations like the following:

- Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
- Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products **within the same category** of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider;
- Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products **in other contraceptive categories** before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in a particular contraceptive category; and
- Imposing an age limit on contraceptive coverage instead of providing these benefits to all individuals with reproductive capacity.

Exceptions Process

If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers must have in place an exceptions process that must be:

- easily accessible,
- transparent,
- sufficiently expedient, and
- not unduly burdensome on the individual or provider (or other authorized representative).

The Departments will consider all relevant facts and circumstances to determine whether a plan's or issuer's exceptions process satisfies the described requirements.

Exceptions Process: Easily Accessible

The Departments will consider an exceptions process to be easily accessible if plan documentation includes relevant information regarding the exceptions process under the plan or coverage, including—

- How to access the exceptions process without initiating an appeal pursuant to the plan's or issuer's internal claims and appeals procedures;
- The types of information the plan or issuer requires as part of a request for an exception; and
- Contact information for a representative of the plan or issuer who can answer questions related to the exceptions process.

Exceptions Process: Transparent

The Departments will consider an exceptions process to be transparent if at a minimum, the information relevant to the exceptions process is included and prominently displayed in plan documents, (including in or along with a summary plan description for ERISA plans), and in any other plan materials that describe the terms of the plan's or issuer's coverage of contraceptive items and services (such as a prescription drug formulary).

- Relevant information would include a standard exception form with instructions, if the plan or issuer uses such a form.
- The Departments also encourage plans and issues to make this information available in a format and manner that is readily accessible, such as electronically (on a website, for example) and on paper.

Exceptions Process: Sufficiently Expedient

This exceptions process must make a determination of the claim according to a timeframe and in a manner that takes into account:

- the nature of the claim (e.g., pre-service or post-service), and
- the medical exigencies involved for a claim involving urgent care.

Plans and issuers are encouraged to develop a standard exception form⁴ with instructions that an attending provider may use to prescribe a particular service or contraceptive based on a determination of medical necessity with respect to the individual involved.

⁴ Similar to the Medicare Part D Coverage Determination Request form
(available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations->)

Exceptions Process (continued)

A plan or issuer does not have an easily accessible, transparent, or sufficiently expedient exceptions process that is not unduly burdensome on the individual (or provider or other individual acting as a patient's authorized representative) if it requires the patient to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process to obtain an exception.

Deference to Attending Provider

- If an individual's attending provider recommends a particular service or FDA approved, cleared, or granted product based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing.
- Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider.
- The plan or issuer must defer to the determination of the attending provider. If the attending provider or patient utilizes the exception process to demonstrate medical necessity, plans and issuers may not overrule the attending provider's determination and must cover the indicated service or item without cost sharing.

How to Ensure Compliance

- **Update or create an exceptions process** for contraceptive products, and provide information about the exceptions process in writing;
- **Review and update plan documents, websites, and other accessible resources** to include information about the exceptions process;
- Review and update exceptions processes to **ensure it is easily accessible, transparent, sufficiently expedient and not unduly burdensome** on consumers;
- Ensure information regarding the availability of, as well as instructions to make use of, the exceptions process is **clearly described to consumers and providers** in plan documents and online resources;
- **Ensure policies and procedures defer** to an individual's attending provider for a determination of the medical necessity of a specific product and/or contraceptive; and
- **Ensure that medical management techniques are permissible** (where frequency, method, treatment or setting for a preventive service are not specified in the recommendation or guideline), **and are not overly-burdensome, inappropriate, or otherwise prohibited.**

Contraception Guidance

- [Affordable Care Act Implementation FAQs \(Set 12\)](#)
- [FAQs About Affordable Care Act Implementation \(Part 26\)](#)
- [FAQs About Affordable Care Act Implementation \(Part 31\)](#)
- [FAQs About Affordable Care Act Implementation \(Part 36\)](#)
- [2019 HRSA-supported Women's Preventive Services Guidelines](#)
 - Note: In December 2021, HRSA approved updates to the Contraception guidelines that apply to plan years starting in 2023. See changes at hrsa.gov/womens-guidelines
- [FAQs About Affordable Care Act Implementation \(Part 51\)](#)
- [FAQs About Affordable Care Act Implementation \(Part 54\)](#)

Q&A

- Questions?
- For additional assistance with compliance with the contraceptive coverage requirements please contact:
 - HHS at: Contraception_Complaints@cms.hhs.gov
 - Department of Labor at: askebsa.dol.gov or by calling toll free at 1-866-444-3272.

Assistance for Consumers

- Consumers who have fully-insured coverage and who have concerns about their health insurance issuer's compliance with these requirements may contact their State Department of Insurance (For contact information, visit https://content.naic.org/state_web_map.htm).
- Consumers who have concerns that their State Department of Insurance is not enforcing the contraceptive coverage requirements may contact CMS at: contraception_complaints@cms.hhs.gov.
- Consumers who are covered by a non-federal, public-sector employer-sponsored plan (such as a state or local government employee plan) and have concerns about their plan's compliance with these requirements may contact CMS at contraception_complaints@cms.hhs.gov or by calling toll free at 1-888-393-2789.
- Consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about their plan's compliance with these requirements may contact the Department of Labor at <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa> or by calling toll free at 1-866-444-3272.
- If an individual is uncertain whether their health coverage is fully-insured or self-insured, they can contact the entity that administers the plan or coverage, or consult plan or coverage documentation for more information. Individuals may also reach out to HHS or DOL by using the contact information above for help finding out the appropriate agency to contact.
- The HHS' Office for Civil Rights (OCR) enforces federal civil rights laws that prohibit discriminatory restrictions on access to health care. If an individual believes that their or another person's civil rights or health information privacy rights have been violated, they can file a complaint with OCR at <https://www.hhs.gov/ocr/complaints/index.html> or call toll-free at 1-800- 368-1019.